

REMARKS

Claims 1, 3-12, 14, 15 and 28-29 are presently pending in the application.

Claim 1 has been amended to incorporate the subject matter from claim 13, now canceled. Claims 16-27 have been canceled without prejudice to the filing of a divisional application directed to the subject matter thereof. No new matter has been added by these amendments, and entry is respectfully requested.

In the present Office Action, the Examiner has rejected claims 1, 3, 4, 14, 15 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,784,161 of Skalsky et al. ("Skalsky") in view of U.S. Patent No. 5,683,443 of Munshi et al. ("Munshi") and a technical article by Gibbs et al. ("Gibbs"). Claims 5-7, 10 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Skalsky, Munshi and Gibbs in view of U.S. Patent No. 6,799,076 of Gelb et al. ("Gelb"). Additionally, claims 8 and 9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Skalsky, Munshi, Gibbs and Gelb in view of U.S. Patent No. 4,440,178 of Bussard et al. ("Bussard"). Further, the Examiner has rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Skalsky, Munshi, Gibbs and Gelb in view of U.S. Patent No. 5,609,611 of Bolz, and claim 13 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Skalsky, Munshi, and Gibbs in view of U.S. Patent No. 6,844,023 of Schulman et al. ("Schulman"). Applicants respectfully traverse these rejections and the arguments in support thereof as follows, and respectfully request reconsideration and withdrawal of the rejections.

Rejection Under § 103(a) Based on Skalsky in view of Munshi and Gibbs

Regarding claims 1, 3, 4, 14, 15, 28 and 29, the Examiner contends that most of the claimed elements are taught by Skalsky, pointing in particular to Figs. 2-5 and 14-19 and columns 5, 6, and 9 of Skalsky. The Examiner acknowledges that Skalsky does not teach that the iridium portion of the alloy is at least 21 weight %. However, Munshi allegedly discloses this concentration in col. 24, lines 42-45 to significantly reduce polarization loss and improve the efficiency of energy transfer through tissue. Therefore, the Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the invention of Skalsky to include an iridium portion of an alloy of at least 21 weight % for the reasons taught by Munshi.

The Examiner also acknowledges that Skalsky does not disclose that the amount of

platinum in the alloy is at least about 100 ppm. However, Gibbs allegedly teaches such a concentration to enhance capacitance and reduce conductance. Therefore, the Examiner concludes that it would have been obvious to have included a platinum portion containing at least about 100 ppm, as taught by Gibbs, in the invention of Skalsky, to enhance capacitance and reduce conductance. Applicants respectfully traverse this rejection as follows.

The stimulation electrode according to the present invention contains a metal base material which is partially covered with an electrically insulating ceramic layer formed of a particular metal oxide or oxynitride. The metal oxide or oxynitride is specifically selected for its electrically insulating properties, and may be formed, for example, by depositing a metallic layer and performing thermal, electrochemical or chemical oxidation, or oxynitriding. As explained in paragraph [0009] of the present application, it has been found that ceramic layer thicknesses of about 1 nm to about 20 μm are particularly advantageous.

In contrast, in Skalsky, an electrically conducting body (electrode) is inserted in a ceramic base member (porous substrate). Skalsky teaches in col. 5, lines 27-30 that the substrate 60 has a central passage 62 for containing the shaft 54 of the electrode 56. Accordingly, the substrate of Skalsky could not be classified as a layer as claimed. Rather, the porous substrate of Skalsky would necessarily have had a thickness of considerably over 20 μm in order to function as described, that is, to be thick enough to define a central passage for receiving an electrode shaft. Skalsky does not teach or suggest the claimed thickness, and such a thickness could not be utilized in the Skalsky invention because it would render the porous substrate unfit for its intended purpose. Specifically, reducing the thickness of the porous substrate of Skalsky to the claimed thickness would reduce its stability, without which it would not be possible to define a central passage for introduction of the shaft of the electrode (see, for example, Figs. 2 and 5 of Skalsky). Accordingly, Skalsky does not teach or suggest the claimed thickness and it would not have been obvious to modify the porous substrate of Skalsky to the thickness of the claimed ceramic layer. Further, as explained below, neither Munshi nor Gibbs teaches or suggests the claimed ceramic layer thickness, and thus even the proposed combination of references would not teach or suggest all of the claimed elements.

Munshi teaches implantable stimulation electrodes which are coated with metal oxides. In the section of Munshi relied upon by the Examiner (col. 24, lines 42-45), Munshi describes an electrode coated with a mixture of ruthenium oxide, iridium oxide, and tantalum oxide in a 50/25/25 ratio. Even if such a mixture were to reduce polarization loss and improve the

efficiency of energy transfer between two stimulation electrodes, as asserted by the Examiner, there is no suggestion that an iridium/platinum alloy coating containing at least 21% iridium, as claimed (and not a mixture of metal oxides), would provide similar results. Further, there is no teaching or suggestion in Munshi as to the thickness of such oxide coatings.

Gibbs describes platinum electrodes and their interaction with alkali halide crystals. Based on Applicants' interpretation of Gibbs, Gibbs does not teach or suggest an iridium/platinum electrically conducting layer containing at least 100 ppm platinum which covers the electrode, as claimed. Therefore, Applicants respectfully traverse the Examiner's interpretation of Gibbs and the rationale for combining Gibbs with Skalsky. Furthermore, there is no teaching or suggestion of coating an electrode with an insulating ceramic layer and thus no suggestion that such a layer should have the claimed thickness.

For all of these reasons, neither Munshi nor Gibbs cures the deficiencies with Skalsky, and even the proposed combination of references would not teach or suggest all of the claimed elements. Accordingly, reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Skalsky in view of Munshi, Gibbs and Gelb

Regarding claims 5-7, 10 and 12, the Examiner acknowledges that none of the previously cited references discloses an electrically conducting layer formed of titanium nitride nor an electrically conducting layer of titanium nitride at least partially covered with at least one oxidation protection layer having a thickness of about 500 nm to about 5 μ m. However, the Examiner contends that Gelb discloses an electrically conducting layer formed of titanium nitride which is at least partially covered with a 500 nm to 5 μ m thick oxidation protection layer on its side facing away from an electrode base member to achieve lower polarization. Therefore, the Examiner concludes that it would have been obvious to modify the invention of Skalsky, Munshi and Gibbs to include the electrically conducting layer taught by Gelb to achieve lower polarization. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of Skalsky, Munshi and Gibbs does not teach or suggest the claimed thickness of the ceramic layer. Gelb teaches a coated electrode having a substrate covered by a first porous layer and a second layer containing iridium. The first layer may contain titanium nitride. However, Gelb does not teach or suggest that the titanium nitride layer has the claimed thickness, and thus Gelb does not cure the deficiency with

the Skalsky/Munshi/Gibbs combination. Accordingly, even the proposed combination with Gelb would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Skalsky, Munshi, Gibbs, Gelb, and Bussard

Regarding claims 8 and 9, the Examiner acknowledges that even the proposed combination of Skalsky, Munshi, Gibbs and Gelb does not teach a ceramic layer arranged adjacent to an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member or a ceramic layer arranged adjacent to at least one oxidation protection layer on an electrically conducting layer of titanium nitride. However, Bussard allegedly teaches these elements to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly. Accordingly, the Examiner concludes that it would have been obvious to have modified the invention of Skalsky/Munshi/Gibbs/Gelb to include these elements, as taught by Bussard, to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of Skalsky, Munshi, Gibbs, and Gelb does not teach or suggest the claimed thickness of the ceramic layer. Bussard teaches a porous electrode containing a sintered member made of electrically conductive particles which may be metal, a metal alloy, a metal compound of tantalum, titanium, niobium, and/or zirconium or a cobalt-chromium-based alloy (col. 1, lines 59-62). However, Bussard does not teach or suggest a ceramic layer covering the sintered member which has the claimed thickness, and thus Bussard does not cure the deficiency with the Skalsky/Munshi/Gibbs/Gelb combination. Accordingly, even the proposed combination with Bussard would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Skalsky, Munshi, Gibbs and Gelb in view of Bolz

Regarding claim 11, the Examiner acknowledges that the Skalsky/Munshi/Gibbs/Gelb combination does not disclose an oxidation protection layer formed of at least one oxide, carbide, nitride, and/or polymer which reduces the impedance of the electrode base member coated with the electrically conducting layer of titanium nitride, or at most increases the impedance to a value

which is smaller than the impedance of the uncoated electrode base member. However, Bolz allegedly discloses such an oxidation protection layer which provides the claimed property to an electrode base member. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art at the time of the invention to have modified the Skalsky/Munshi/Gibbs/Gelb invention to include the oxidation protection layer of Bolz to provide the desired impedance reduction or increase, as taught by Bolz, for picking up heart signals for which the low temperature frequency range is particularly important, especially in the region where the signals are weak. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of Skalsky, Munshi, Gibbs, and Gelb does not teach or suggest the claimed thickness of the ceramic layer. Bolz teaches a stimulation electrode containing a porous surface coating made of an inert material, which may be a nitride, carbide, carbonitride or pure element or alloy of gold, silver, titanium, iridium, platinum or carbon (col. 9, lines 22-23 and col. 10, lines 49-53). The titanium nitride, carbide, and carbonitride materials taught by Bolz are not metal oxides or oxynitrides are claimed, and also are not electrically insulating ceramic materials, but are in fact electrically conductive materials. Further, Bolz does not teach or suggest that such a surface coating has the claimed thickness, and thus Bolz does not cure the deficiency with the Skalsky/Munshi/Gibbs/Gelb combination. Accordingly, even the proposed combination with Bolz would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Skalsky, Munshi, and Gibbs in view of Schulman

Finally, regarding claim 13, the Examiner acknowledges that the proposed Skalsky, Munshi, and Gibbs combination does not teach a ceramic layer having a thickness of about 1 nm to about 20 μm . However, Schulman allegedly discloses a ceramic layer having such a thickness to protect microminiature components and devices intended to be implanted in living tissues. Therefore, the Examiner concludes that it would have been obvious to modify the invention of Skalsky/Munshi/Gibbs to include a ceramic layer having the thickness taught by Schulman for this purpose. Applicants respectfully traverse this rejection as follows.

Claim 13 has been canceled by this amendment, rendering this rejection moot.

Applicants submit that the rejection is also not relevant to claim 1, which incorporates the subject matter of claim 13, as follows.

Schulman teaches a biocompatible coating which protects and insulates a device to be implanted in living tissues. The coating comprises thin layer(s) of ceramic which are less than 25 microns thick. Despite the Examiner's assertion to the contrary, there would have been no motivation to replace the porous substrate of Skalsky with the thin coating of Schulman. In fact, as previously explained, such a modification would have rendered the invention of Skalsky unfit for its intended purpose because the coating of Schulman would not have enough stability to define a passage for introduction of an electrode shaft. Accordingly, even the proposed combination with Schulman would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

In view of the preceding Amendments and Remarks, it is respectfully submitted that the pending claims are patentably distinct from the prior art of record and in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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